IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)))))))))	C. A. No. 06-222 (JJF)

WYETH'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS

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Pursuant to the Court's Discovery Dispute procedures at paragraph 4 of the Rule 16 Scheduling Order (D.I. 27 ¶ 4), Plaintiff Wyeth moves to compel the production of certain categories of documents from Defendant Impax Laboratories, Inc. ("Impax").

I. The Court Should Order Impax To Produce All Documents Concerning The Patents-In-Suit, Wyeth's Commercial Embodiment Of The Patents-in-Suit - Effexor® XR; Impax's Decision To Develop And Market An Extended Release Venlafaxine Product; And Impax's Decision To File Its ANDA

Wyeth's document requests seek production of documents concerning:

- the patents-in-suit, including Impax's knowledge and non-privileged communications concerning those patents (E.g., Louden Decl., Ex. 1, Doc. Req. No. 40, 41, 87; Ex. 2 at 2-3; Ex. 4 at 1-2);

- Effexor® XR, Wyeth's commercial embodiment of the patents-in-suit (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 50, 52, 86; Ex. 4 at 2);

- Impax's decision to develop and market an extended release venlafaxine product (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 23, 25, 26, 27, 28, 69; Ex. 2 at 3; Ex. 4); and

- Impax's decision to file its ANDA (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 23, 26, 27, 28; Ex. 2 at 3).

To date, Impax has produced only its ANDA, and contends, in essence, that Wyeth is not entitled to any of the discovery Wyeth seeks above until after liability is determined, if at all, merely because Wyeth has withdrawn its willfulness claim. E.g., Louden Decl., Ex. 3 at 4; Ex. 5 at 2-3; Ex. 6 at 2. Impax's position is untenable.

There can be little question that Wyeth is entitled to full discovery on the patents and products that are at the heart of this litigation. The requested discovery is directly relevant to claim construction, validity, and infringement issues that *presently* are in the case. For example, information concerning Impax's knowledge and understanding of the teachings in the patents-in-suit at the time Impax developed its own products and the influence of those teachings on that development process are relevant to claim construction, infringement under the doctrine of equivalents, and Impax's argument that the patents-in-suit do not enable others to practice the inventions. Whether Impax set out to substantially copy Wyeth's Effexor® XR products or independently developed its products is relevant to infringement under the doctrine of equivalents as well as nonobviousness. Impax's recognition of the commercial success of

Wyeth's patented Effexor® XR product and Impax's consideration of that success in deciding to develop the accused infringing products are relevant to the secondary considerations of non-obviousness. *See, e.g., Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 36 (1997) (the presence or absence of independent development is relevant to known interchangeability under the doctrine of equivalents); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) (secondary considerations such as commercial success and copying are indicia of nonobviousness); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*) (how one of ordinary skill in the art interprets the patent is relevant to claim construction); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285, 1287 (objective considerations such as copying is probative evidence of nonobviousness; development evidence of copying supports a claim of infringement under the doctrine of equivalents).

There is no basis to defer discovery on these issues until after a liability determination as Impax suggests because, as the foregoing demonstrates, this discovery is not limited to the issue of whether this is an exceptional case, but is totally intertwined with the validity and infringement contentions at the heart of the case. Moreover, Impax confuses the timing of a decision on the exceptional case issue with discovery concerning that issue. *See Rohm & Haas Co. v. Mobil Oil Corp.*, 654 F. Supp. 82, 84 (D. Del. 1987) ("to reserve decision until after the damages phase is not equivalent to declaring when evidence on the issues of willfulness, exceptionality, and attorney fees can or should be discovered and presented to a court"). Evidence concerning Impax's understanding of and reliance on the teachings in the patents-in-suit to develop its own products and its decision to file its ANDA on those products notwithstanding that reliance, especially in view of Impax's knowledge of the money it could make marketing a generic copy of Wyeth's commercially successful product, likewise would support Wyeth's assertion that Impax's non-infringement and invalidity contentions are baseless. Thus, separating out exceptional case discovery from discovery on the liability issues would likely prove impossible.

Impax's request for a stay of discovery pending a liability determination would unjustifiably bifurcate this case in a manner that would burden this Court with an unnecessary and virtually indistinguishable second discovery period and trial. *See, e.g., Johns Hopkins Univ. v. CellPro*, 160

F.R.D. 30, 36 (D. Del. 1995) ("Staying discovery . . . builds difficult delays and complications into the case."). Efficient case management clearly compels the conclusion that discovery pertaining to the exceptional case issue, which overlaps significantly with the issues of infringement and validity, is entirely appropriate during the liability phase of this litigation, and should not be stayed.

II. The Court Should Order Impax To Produce Documents Concerning Its Consideration Of Any Immediate Release Venlafaxine Product Or Alternate Extended Release Venlafaxine Formulations Prior to the Filing of Its ANDA

Wyeth has requested that Impax produce documents concerning:

- its consideration of development of a generic immediate release venlafaxine formulation prior to the filing of ANDA 78-057 (E.g., Louden Decl., Ex. 1, Doc. Req. Nos. 18, 28, 44, 47; Ex. 2 at 1; Ex. 4 at 1-2);

- comparisons between immediate release venlafaxine and extended release venlafaxine (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 11, 44, 46-47; Ex. 4 at 2);

- nausea and/or vomiting in humans associated with immediate release venlafaxine (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 11, 44, 46-47; Ex. 2 at 2; Ex. 4 at 2); and

- its consideration of any alternate extended release venlafaxine product prior to the filing of its ANDA No. 78-057 (E.g., *Id.*, Ex. 1, Doc. Req. Nos. 23, 25-27, 28, 42, 43, 45, 48, 51-54, Ex. 2 at 1; Ex. 4).

Impax has objected to such production, contending that "[d]ocuments regarding products that are not the subject of ANDA 78-057, are not accused in this litigation, and are not related to EFFEXOR® or EFFEXOR® XR are not relevant to the claims at issue in this litigation." Louden Decl., Ex. 3 at 3. It further has represented that it would withhold such documents even if consideration of alternative formulations led to the filing of the present ANDA. *Id.*, Ex. 5 at 2. This position is unsupportable.

Impax has alleged that the patents-in-suit are invalid as obvious. Wyeth is entitled to rebut this contention by pointing to the unexpectedly improved results of the claimed invention. *See, e.g. Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004). Wyeth contends that one of the advantages of the invention over the prior art is that the claimed extended release venlafaxine dosage forms have an unexpectedly improved side effects profile compared to immediate release venlafaxine dosage forms. For example, several of the asserted method claims refer to a reduction in nausea and emesis relative to immediate release venlafaxine. Evidence of unexpectedly improved side

effect profiles further supports the nonobviousness of Wyeth's inventions. Moreover, Impax disputes this contention and has asserted that Wyeth committed inequitable conduct with respect to the discussion of clinical trial results in the patents. Thus, any Impax documents that discuss the side effects profile of either extended release or immediate release dosage forms of venlafaxine are relevant to rebut Impax's allegations of obviousness and inequitable conduct. Moreover, discovery concerning Impax's research, development and testing prior to filing its ANDA No. 78-057 of any alternative extended release venlafaxine formulations and Impax's reasons for choosing its present formulation is relevant not only to Impax's interpretation of the patents-in-suit, but also to any efforts by Impax to copy the patents, as well as Impax's views as to the interchangeability of various ingredients and thus their substantial equivalence. For example, Impax's rejection of formulations that do not have substantially the same *in vitro* dissolution profiles as those disclosed in the patents and achieved by Effexor® XR is relevant to copying, infringement and enablement.

III. Conclusion

For the foregoing reasons, the Court should order Impax to produce all non-privileged documents concerning: (1) the patents-in-suit, (2) Effexor® XR, (3) Impax's decision to develop and market an extended release venlafaxine product, (4) Impax's decision to file ANDA No. 78-057, (5) Impax's consideration of alternate extended release venlafaxine formulations prior to the filing of ANDA No. 78-057, (6) Impax's consideration of development of a generic immediate release venlafaxine formulation prior to the filing of ANDA 78-057, (7) comparisons between immediate release venlafaxine and extended release venlafaxine, and (8) nausea and/or vomiting in humans associated with immediate release venlafaxine; and to log on a withheld document list privileged documents concerning the same topics.

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RULE 7.1.1 CERTIFICATE

Pursuant to D. Del. L.R. 7.1.1, counsel for Wyeth certifies that they have discussed the subject matter of this motion with counsel for Impax and they have not been able to reach agreement on the matters therein.

/s/ Karen Jacobs Louden
Karen Louden (#2881)

CERTIFICATE OF SERVICE

I, Karen Jacobs Louden, hereby certify that on September 18, 2006, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on September 18, 2006 upon the following in the manner indicated:

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